

AMENDMENTS TO THE DRAWINGS

Applicants submit herewith a Substitute Sheet depicting Figure 24B corrected according to the requirements set forth by the Examiner in the present Office Action.

REMARKS

Entry of the foregoing amendments, reconsideration, and reexamination of the subject application as amended pursuant to and consistent with 37 C.F.R. § 1.111, in light of the remarks which follow, are respectfully requested.

1. Status of the Claims

Claims 54-97 are pending. Claims 78, 80, 81 and 84-93 stand withdrawn. Claims 54-77, 79, and 94-97 stand rejected. Claims 82 and 83 stand objected to, but are indicated as allowable if rewritten to include all the limitations of the intervening base claims.

The Office Action indicates that the restriction has been made final. Additionally, claims 78, 80, 81, and 84-93 have been withdrawn as elected to non-elected subject matter.

Applicants have cancelled claims 74-75 and 77. Applicants have amended claims 54, 72 and 97 and introduced new claim 98. Support for the claims amendments can be found for example within the original claims; page 11, line 29; and page 12, line 10 to page 14, line 2. Accordingly, Applicants submit that no prohibited new matter is entered by way of the amendment. Applicants reserve the right to file a continuation or divisional application on any subject matter cancelled by way of amendment.

2. Objection to the Drawings

Figure 24B is objected to for reciting “GLP-1 (7-36)NH” instead of “GLP-1 (7-36)NH₂”. Applicants submit herewith substitute Figure 24B which amends the figure to recite “GLP-1 (7-36)NH₂”. As this corrects a typographical error which would have been readily understood, it is believed no prohibited new matter is introduced by entry of the substitute figure. With the amendment, Applicants respectfully request withdrawal of the objection.

3. Objection to the Specification

The disclosure is objected to because the description of Figure 24 recites “C” and “D” whereas Figure 24 shows “A” and “B.” Additionally, the Office objects to the specification’s description of Figure for reciting “GLP-1(G)” and the misspelling of “NaCl.”

Applicants have amended the specification above to refer to “A” and “B”. Applicants have also changed the description to refer to “GLP-1 (7-36)NH₂, in correspondence with the figure and amendment sodium chloride. Given the nature of the amendments, Applicants

believe that no prohibited new matter is introduced by entry of these amendments. With these amendments, Applicants respectfully request withdrawal of the objection.

4. Objection to the Claims

Claim 97 is objected to as depending from non-elected claims 84-89. Applicants have amended claim 97 such that it no longer recites to claims 84-89. Accordingly, with the amendment, the objection to the claims should be withdrawn.

5. Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 54-77, 79 and 94-96 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office rejects the claims, because claims 54-62, 68, 72, 73, and 76 do not limit a peptide of interest by either structure or function.

Without acquiescing to the merit of the rejection, Applicants have amended claims 54 and 72, and thereby the claims dependent thereon, to recite GLP-2 derivatives. Applicants submit that with the amendments to the claims, a skilled artisan would have been placed in position of the subject matter at the time. Accordingly, Applicants submit the rejection has been mooted and should be withdrawn.

6. Claim Rejections under 35 U.S.C. § 112, First Paragraph

The Office rejected claims 54-77, 79, and 94-96 under 35 U.S.C. § 112, first paragraph as allegedly lacking a sufficiently enabling disclosure. The Office admitted that while the specification is “enabling for....fusion proteins wherein a given GLP-1 derivative is substituted by any of GLP-1 derivatives recited in the specification (pages 12-13)...” it does not reasonably provide enablement for a process of making a peptide of any structure and/or function or GLP-1 derivative using other helper and protective peptides.

Without acquiescing to the merits of the rejection, Applicants have amended claims 54 and 72 to recite the GLP-1 derivative from pages 12-14, which the Office admits is enabled, thereby mooted the rejection. Applicants respectfully request withdrawal of the rejection.

7. **Claim Rejections under 35 U.S.C. § 112, Second Paragraph**

Claim 97 is rejected under 37 C.F.R. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claiming the subject matter which applicant regards as the invention. The Office asserts that claim 97 is confusing for reciting “the fusion protein as described by any one of claims 82-89” wherein claims 82-89 are drawn to a process.

Applicants have amended the claim to refer to specific sequence identifiers instead of to claims 82-89 thereby mooting the rejection. Applicants request allowance of the claims in view of the amendment, given that the Office indicated the claim would be allowable if rewritten to overcome the objection/rejections.

8. **Claim Rejections Under 35 U.S.C. § 102**

Claims 54-77, 79 and 94-96 are rejected under 35 U.S.C. § 102(e) as being anticipated by Suzuki et al. (U.S. Patent No. 5,891,671). The Office alleges that Suzuki et al. (U.S. Patent No. 5,891,671) [hereinafter the ‘671 patent] teaches the production of the 7-37 fragment of glucagon-like peptide-1 using an *E. coli* transformed with a DNA encoding a fusion protein comprising the protective peptide, helper peptide and 7-37 GLP-1 (columns 5 and 6, columns 17-20, Examples 11-14, claim 13). Said protective peptide is a fragment of *E. coli* β -galactosidase that is allegedly in the current claims and cleavage site is allegedly a Kex2 protease cleavage site as claimed.

Applicants traverse the rejection as to the amended claims. The ‘671 patent does not teach or suggest the GLP-1 derivatives recited in claims 54 and 72 as amended. Additionally, claims 54-71 and 79, and 94-97 are directed to a process. This process uses two processing points. The ‘671 patent does not teach processing points, only one. Instead the ‘671 patent is characterized by the use of base rich region (such as His) in a linker peptide to enhance the action of a processing enzyme (Kex2). As the reference does not teach all the limitations of the claims, no *prima facie* case of anticipation can be adduced. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

CONCLUSION

In conclusion, this is believed to be in full response to the outstanding restriction requirement. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573.

Respectfully submitted,
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